

REMARKS

After entry of this amendment, claims 2, 3, 4, 6, 9, 19, and 50-54 are pending. Claims 2, 3, 4, 9 and 19 have been amended. Claims 1, 5, 7, 8, 10-18 and 20-49 have been cancelled without prejudice to filing in one or more continuation applications. New dependent claims 50-54 have been added.

Claims 2, 3, 6 and 19 have been amended to improve the clarity thereof. Support for the amendments to claims 2 and 19 can be found e.g., at page 13, lines 13-26; and page 60 lines 11-12. The wording of claim 3 has been amended to avoid duplication with claim 2, from which it depends. Claim 6 has been amended to more clearly recite a method step. New dependent claims 50-52 are supported by claims 6, 3 and 4, respectively, and depend from claim 19. New dependent claims 53 and 54 serve to further characterize the detection of Cpn10 by specifying that such detection is conducted using mass spectrometry. Support for claims 53 and 54 can be found in various sections of the specification and in Example 3 thereof. No new matter is added.

Rejections Under 35 USC 112 (first paragraph)

a) Claims 2-4, 6, 8 and 9

Claims 2-4, 6, 8 and 9 stand rejected for allegedly lacking enablement in the specification.

The Examiner admits that the specification is enabling for “a method of screening for endometrial cancer in a subject, the method comprising, (a) detecting the levels or amount of chaperonin 10 (CPN10) as set forth in SEQ ID NO:1 in an endometrial cancer sample obtained from the subject and (b) comparing the levels of CPN10 in step (a) with the levels or amount of CPN10 in a control endometrial tissue sample, wherein increased levels of CPN10 protein expression in the sample obtained from the subject is indicative of endometrial cancer.”

However, the Examiner asserts that the specification does not provide enablement for the breadth of the claims as recited. Specifically, the Examiner asserts that (using the numbering provided by the Examiner):

- ii) *the term “biological sample” encompasses non-operative embodiments;*
- iv) *CPN10 as used in the claims would require undue experimentation; and*
- v) *determination of the muteins of CPN10 encompassed by the claims would require undue experimentation for one of skill in the art based on the unpredictability of proteomics and the large number of muteins claimed.*

Applicants request reconsideration and withdrawal of these rejections for the following reasons.

Claim 8 has been cancelled. Thus, this rejection is moot as to that claim.

Claim 2 has been amended to further clarify the sequence of human chaperonin 10 (Cpn10) and the biological sample used in the claimed method. Applicant has also clarified the difference in the detected protein amounts that are used in the method. .

The Examiner admits that the claimed method is enabled for detecting CPN10 having the sequence corresponding to SEQ ID NO:1. In addition, Applicant has further referred in the specification to sequences having at least 90% identity to SEQ ID NO:1. This feature is clearly supported by the specification and would be clearly understood by persons skilled in the art. See, e.g., page 17, line 13, to page 18, line 19 and 28-30, wherein a discussion is provided of the natural variations in sequences corresponding to, *inter alia*, Cpn10¹.

Applicant submits that claim 2, as amended, and all of its dependent claims 2-4, 6 and 9, are fully supported and enabled by the specification.

b) *Claims 19-21*

Claims 19-21 stand rejected for lacking enablement in the specification. The Examiner asserts that the prior rejections that remain are:

¹ It is noted that variations in the amino acid sequence of Cpn10 are known in the art. See, e.g., the NCBI web site (<http://www.ncbi.nlm.nih.gov/snp>) wherein various SNPs are described for human chaperonin 10, some of which result in an amino acid change in the CPN10 amino acid sequence.

- 1) *the term “biological sample” encompasses non-operative embodiments;*
- 2) *CPN10 as used in the claims would require undue experimentation; and*
- 3) *the methods recited in claims 19-21 represent “an invitation to the skilled artisan to undertake further research to discover the parameters needed to carry out the goals of the methods”.*

Applicants request reconsideration and withdrawal of these rejections for the following reasons.

Claims 20 and 21 have been cancelled without prejudice. Therefore, the rejection as to those claims is moot.

Claim 19 has been amended in a manner similar to claim 2 to clarify the meaning of biological sample and to recite only human chaperonin 10 having the sequence of SEQ ID NO: 1 or a sequence having 90% identity therewith. Therefore, the Examiner's rejections with regard to these features of the claim are believed to be overcome by the amendments made herein.

Further, the language of claim 19 has been amended to further clarify the claimed method and to more clearly specify that the level or amount of Cpn10 is measured at two time intervals and the progression of cancer is indicated where the level or amount at the second time interval is greater than at the first measurement. Human chaperonin 10 is shown in the specification to be differentially expressed in patients with and without endometrial disease. Because an increase in Cpn10 is indicative of cancer, when the Cpn10 levels are measured in the same patient, one of skill in the art would readily ascertain and understand that an increased level of the cancer biomarker at a later time would indicate that the cancer in that particular patient has progressed. An undue amount of experimentation would not be required of one of skill in the art in order to practice the claimed method. Applicant submits that such a method is clearly supported and enabled by the present specification.

Applicants respectfully request that the Examiner withdraw the above rejections.

Rejections Under 35 USC 102(a) and 103(b)

Claims 2-4, 8 and 9 stand rejected as being anticipated or, in the alternative, obvious in view of Warrington et al. (US 2001/0044104). Claim 6 has not been included in this rejection.

Claim 2 has been amended to more clearly specify that the claimed method comprises the finding of an elevated or increased level or amount of Cpn10 in the sample, relative to a control. Applicant submits that such step is not taught or suggested by Warrington et al.

Applicant respectfully requests that the Examiner withdraw the above rejections and allow all pending claims to proceed to issue.

Respectfully submitted,

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Dated: June 2, 2011

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